IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

Plaintiffs in re: Depakote	Master Case No.: 3:18-cv-1198-NJR Judge: Hon. Nancy J. Rosenstengel
This document relates to: **B.P.** by his next friends Randolph H. Krings and Susan L. Matson-Krings and **ANN SCHOLZ** Plaintiffs, v. **ABBOTT LABORATORIES INC.** and **ABBVIE INC.** Defendants.	Case No. 3:19-cv-278-NJR **FIRST AMENDED COMPLAINT** **WITH JURY DEMAND ENDORSED HEREON**

Plaintiffs B.P. by his next friends Randolph H. Krings and Susan L. Matson-Krings and Ann Scholz, for their Complaint against Defendants Abbott Laboratories Inc. and AbbVie Inc., hereby state and aver:

Prior Action

1. Plaintiffs originally brought this action in the Circuit Court of Cook County, Illinois. It was subsequently removed to the Northern District of Illinois (case No. 1:18-cv-1161) and then dismissed without prejudice.

Nature of the Action

2. This is an action for damages suffered by Plaintiffs and caused by Defendants' prescription medication product known as Depakote. Plaintiff Ann Scholz took Depakote while

pregnant with B.P. Plaintiffs allege the product was unreasonably unsafe and caused in B.P., among other things, neurobehavioral disorders and cognitive impairments that are permanent, profound, and debilitating. These include pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention deficit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote. Plaintiff Ann Scholz, parent of B.P., additionally alleges loss of consortium with B.P. caused by Defendants' defective product.

Parties

3. Plaintiff B.P. is a minor who is a natural person and is a resident of Lake County, California. Randolph H. Krings and Susan L. Matson-Krings bring this action on B.P.'s behalf.

4. Plaintiff Ann Scholz is a natural person, is a resident of Lake County, California and brings this suit in her individual capacity as well.

5. Defendant Abbott Laboratories, Inc. now is, and at all times relevant to this action was, a corporation organized and existing under the laws of the State of Delaware, with its principal place of business and its headquarters in the State of Illinois. Abbott may be served by delivering the citation to its registered agent for service: CT Corporation System, 208 S. LaSalle St., Suite 814, Chicago, IL, 60604.

6. Abbott engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, selling, and introducing into the stream of commerce products known as Depakote and Depakote ER. Abbott sold and marketed its Depakote and Depakote ER products in this District, in Massachusetts, and throughout the United States.

7. Defendant AbbVie, Inc. now is, and at all times relevant to this action was, a corporation organized and existing under the laws of the State of Delaware, with its principal place of

business and its headquarters in the State of Illinois. AbbVie may be served by delivering the citation to its registered agent for service: The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, DE 19801.

8. AbbVie is described on Abbott's website as a new, independent biopharmaceutical company composed of Abbott's former proprietary pharmaceutical business. On information and belief, as of January 1, 2013, AbbVie, Inc. is the successor in interest to one or more divisions of Abbott Laboratories that were in existence prior to AbbVie's incorporation.

Facts

Depakote Background

9. Defendants are and at all relevant times have been engaged in the business of formulating, designing, manufacturing, licensing, testing, advertising, marketing, warranting, selling, distributing, and introducing into the stream of commerce a drug compound known as "divalproex sodium," "valproic acid," or "valproate," which Defendants have sometimes marketed under brand names such as "Depakote," "Depakote ER," "Depakene," and "Depacon."

10. Regardless of the name under which Defendants marketed, sold, and distributed the drug, all of its forms were and are, for all purposes relevant to Plaintiffs' claims, chemically and pharmacologically identical. For purposes of this Complaint, these various forms and names of the drug compound will all be referred to by the common brand name "Depakote."

11. Defendants formulated, designed, manufactured, licensed, tested, advertised, marketed, warranted, sold, and distributed Depakote and, in approximately 1978, after receiving approval to market Depakote in the United States for treatment of certain forms of epilepsy, Defendants began marketing and placing Depakote into the stream of commerce throughout the United States. Depakote was promoted as an effective anti-epileptic drug ("AED").

12. Depakote was and is defective and unreasonably dangerous for its intended use. In particular, the primary compound in Depakote, valproic acid, has been established to cause birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

13. Defendants knew or should have known Depakote was a human teratogen (i.e., that it causes malformations of the embryo or fetus) and that it should not be prescribed to pregnant women or women of childbearing years who may become pregnant.

14. Depakote teratogenicity was published in medical literature in 1980, within two years of the initial introduction of Depakote to the market. In 1982, the association between Depakote and neural tube defects was documented. By 1983, a twenty-fold increase in the rate of spina bifida among infants exposed to Depakote during fetal development was reported in medical literature. In 1984, "fetal valproate syndrome" was a defined term in the medical literature. Defects associated with fetal valproate syndrome include, among other disorders: characteristic facial features, major malformations, learning disabilities, and central nervous system dysfunction.

15. The occurrence of neural tube defects (such as spina bifida) from fetal exposure to Depakote is estimated to be as high as 5% of all births, compared to approximately 0.1% in the general population.

16. Cleft palates, cardiac defects, hypospadias, and skeletal abnormalities are other congenital defects characteristic of exposure to Depakote during early pregnancy.

17. Craniofacial abnormalities caused by Depakote exposure in utero include trigonocephaly (triangular shaped head due to premature fusion of metopic suture), a tall forehead with bilateral narrowing, flat nasal bridge, broad nasal root, anteverted nostrils, small jaw, abnormalities of the lip and philtrum, epicanthic folds, and midface hypoplasia.

18. Radial ray and tibial ray defects (deformation of bones in forearm and lower leg), multiple, missing, overlapping, or deformed fingers and toes, extremely elongated fingers or

toes, and talipes equinovarus (club foot) are some of the skeletal defects caused by Depakote exposure in utero.

19. Bilateral congenital cataract, optic nerve hypoplasia, and other defects of the iris and cornea are abnormalities of the eyes caused by Depakote exposure in utero.

20. Ventricular septal defects, aortic and/or pulmonary stenosis, coarctation of the aorta, and atrial septal defect are some of the congenital heart defects caused by Depakote exposure in utero.

21. Birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders are known to result directly from exposure to Depakote, either singly or in some combination with each other.

22. Medical research has also concluded Depakote exposure causes a significant increase in risk of autism spectrum disorder (which includes classic autism, Asperger's syndrome, pervasive development disorder not otherwise specified, childhood disintegrative disorder, and Rett syndrome), childhood autism, atypical autism, and other neurobehavioral disorders.

23. Scientific articles single out Depakote as among the most—if not the most—teratogenic of all AEDs. One study in 1995 reported an incidence rate of neural tube defects (such as spina bifida) ten times greater than with other AEDs. Another study found major congenital abnormalities in eleven percent of all infants exposed to Depakote during the earliest weeks of pregnancy.

24. As pharmaceutical research and development progressed through the 1980s and 1990s, new and better AEDs were developed and approved, which proved as effective as Depakote at controlling most seizures in most epileptic patients, but which bore far less risk of harming infant development in utero.

25. Medical researchers have confirmed that while Depakote is effective at controlling seizures, it is also riskier than other modern AEDs for women who are pregnant or who may become pregnant. The risk posed by Depakote use is not only higher than the risk posed by no AED use, but is also higher than the risk posed by other AEDs taken by women with epilepsy during their pregnancies.

26. Defendants have been aware of the birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders associated with Depakote on early term pregnancies before and while they marketed and distributed Depakote in the United States.

27. Despite this emerging scientific consensus, Defendants refused to communicate the true nature and extent of the risk in its product labeling and warnings to physicians and consumers.

28. Instead of warning doctors and women of childbearing age about the sharply heightened risks of ingesting Depakote during pregnancy, Defendants have sought to minimize and downplay the risks and dangers in their product labeling and promotion of Depakote.

29. On information and belief, Defendants have aggressively tried to market Depakote to pregnant women by reassuring them that taking folic acid reduces the risk of birth defects without clarifying that they had little or no evidence folic acid was effective in reducing or eliminating the risk of cognitive impairment, neurobehavioral disorders, or some physical defects, even if it did somewhat reduce the risk of neural tube defects.

30. Furthermore, despite the risks of major congenital malformations, cognitive impairment, and neurobehavioral disorders, Defendants have aggressively pursued expansion of the uses for which Depakote is approved and marketed to doctors and patients.

31. As early at the mid-1990s, Defendants implicitly and explicitly promoted Depakote to doctors, consumers, and the general public for unapproved or "off-label" uses, such as for

treatment of mild depression, the depressive state of bi-polar disorder, and chronic pain conditions such as migraine headaches.

32. In an agreed statement of facts filed as part of a criminal plea agreement, Abbott acknowledged it promoted Depakote for off-label uses with no evidence of its effectiveness for those uses.

33. Abbott also entered into a related civil settlement with the Department of Justice for its illegal off-label promotion of Depakote:

> The civil settlement addresses broader allegations by the United States that from 1998 through 2008, Abbott unlawfully promoted Depakote for unapproved uses, including behavioral disturbances in dementia patients, psychiatric conditions in children and adolescents, schizophrenia, depression, anxiety, conduct disorders, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol and drug withdrawal, attention deficit disorder and autism. Some of these unapproved uses were not medically accepted indications for which the United States and state Medicaid programs provided coverage for Depakote. The United States contends that this promotion included, in part, making false and misleading statements about the safety, efficacy, dosing and cost-effectiveness of Depakote for some of these unapproved uses, and claiming use of Depakote to control behavioral disturbances in dementia patients would help nursing homes avoid the administrative burdens and costs of complying with OBRA regulatory restrictions applicable to antipsychotics.
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> The civil settlement also covers allegations that Abbott offered and paid illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly and unduly influence the content of company sponsored Continuing Medical Education programs, in violation of the Federal Anti-Kickback Statute. The claims settled by the civil agreement are allegations only and there has been no determination of liability, except to the extent that Abbott has admitted facts in the civil settlement agreement or in the criminal plea and agreed statement of facts filed in the criminal action.

USDOJ: Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote. http://www.justice.gov/opa/pr/2012/May/12-civ-585.html.

34. Defendants have promoted these off-label uses even though there are other drugs which are as effective or more effective for treatment of those conditions, and which do not involve the

severe risk of birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders associated with Depakote.

35. In further pursuit of market share in the pharmaceutical industry, Defendants have worked aggressively to manipulate the regulatory system and gain approval for certain of these off-label uses, in hopes of concealing within government approval the dangers of using Depakote for conditions in which its use is unnecessary.

36. Defendants have concealed risks from and otherwise misled doctors who prescribe Depakote and monitor patients' drug regimen during pregnancy. Despite knowing the extremely high incidence rate of major congenital malformations in babies born to women who take Depakote while pregnant (one study suggested a risk of up to one in every five pregnancies, while others have found the risk is at least one in ten), Defendants continue to downplay the risks and refuse to provide adequate information in the Depakote label and package inserts regarding the true scope and severity of the dangers. Instead, Defendants insist on using muted and understated language to suggest that women of childbearing age weigh the "potential risks," when in fact the risks are severe, are well-known to Defendants, and, in scientific reality, are in excess of the injuries and incident rates reported in the label.

37. In direct contradiction to the truth, Defendants claimed in the product labeling from 1978 until 2006 that any potential increase in birth defects from Depakote was only a possibility, and that the risk was common to the entire class of antiepileptic drugs.

38. Defendants denied in the product labeling for Depakote that a cause-and-effect relationship between the use of Depakote and birth defects had been proven, and claimed instead that the increased incidence of birth defects could be attributed to methodological problems in the data, genetic causes, or to risks arising from the epileptic condition itself.

39. On July 15, 2013 Defendants issued a Dear Doctor Letter entitled "Important Drug Warning," in which they announced major safety labeling changes for Depakote, including "Changes to Boxed Warning," "Important Limitations of Use in Women of Childbearing Potential," and "Pregnancy Category X for Prophylaxis of Migraine Headaches" for all valproate products. As part of the label change, Defendants strengthened and clarified the "Black Box" warning in regard to teratogenicity:

> **Fetal Risk**
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> Valproate can cause major congenital malformations, particularly neural tube defects (e.g., spina bifida). In addition, valproate can cause decreased IQ scores following in utero exposure.
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> Depakote and Depakote ER are therefore contraindicated in pregnant women treated for prophylaxis of migraine. Valproate should only be used to treat pregnant women with epilepsy or bipolar disorder if other medications have failed to control their symptoms or are otherwise unacceptable.
>
> Depakote Sprinkle Capsules should only be used to treat pregnant women with epilepsy if other medications have failed to control their symptoms or are otherwise unacceptable.
>
> Valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition. This is especially important when valproate use is considered for a condition not usually associated with permanent injury or death (e.g. migraine). Women should use effective contraception while using valproate.

40. In addition, Defendants revised the WARNINGS AND PRECAUTIONS sections of the labels of Depakote, Depakene, and other valproate products:

> Birth Defects
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> - Valproate can cause fetal harm when administered to a pregnant woman. Pregnancy registry data show that maternal valproate use can cause neural tube defects and other structural abnormalities (e.g., craniofacial defects, cardiovascular malformations and malformations involving various body systems). The rate of congenital malformations among babies born to mothers using valproate is about four times higher than the rate among babies born to epileptic mothers using other anti-seizure monotherapies. Evidence suggests that folic acid supplementation prior to conception and during the first trimester of pregnancy decreases the risk for congenital neural tube defects in the general population.

Decreased IQ Following in utero Exposure

- Valproate can cause decreased IQ scores following in utero exposure. Published epidemiological studies have indicated that children exposed to valproate in utero have lower cognitive test scores than children exposed in utero to either another antiepileptic drug or to no antiepileptic drugs. The largest of these studies is a prospective cohort study conducted in the United States and United Kingdom that found that children with prenatal exposure to valproate (n=62) had lower IQ scores at age 6 (97 [95% C.I. 94- 101]) than children with prenatal exposure to the other antiepileptic drug monotherapy treatments evaluated: lamotrigine (108 [95% C.I. 105–110]), 104–112]). It is not known when during pregnancy cognitive effects in valproate-exposed children occur. Because the women in this study were exposed to antiepileptic drugs throughout pregnancy, whether the risk for decreased IQ was related to a particular time period during pregnancy could not be assessed.
- Although all of the available studies have methodological limitations, the weight of the evidence supports the conclusion that valproate exposure in utero can cause decreased IQ in children.
- In animal studies, offspring with prenatal exposure to valproate had malformations similar to those seen in humans and demonstrated neurobehavioral deficits.
- Valproate is contraindicated during pregnancy in women being treated for prophylaxis of migraine headaches. Women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant should not be treated with valproate unless other treatments have failed to provide adequate symptom control or are otherwise unacceptable. In such women, the benefits of treatment with valproate may still outweigh the risks.

Use in Women of Childbearing Potential

- ...It is not known whether the risk of neural tube defects or decreased IQ in the offspring of women receiving valproate is reduced by folic acid supplementation. Dietary folic acid supplementation both prior to conception and during pregnancy should be routinely recommended for patients using valproate.

41. As a result of these warnings, Depakote and related products are labeled Category X for pregnancy for the indication of migraine. They remain Category D for bipolar disorder and seizure disorder, but may only be used in pregnancy as drugs of last resort.

42. Defendants waited 30 years to warn that Depakote is a drug of last resort during pregnancy, and that it is completely contraindicated during pregnancy for the treatment of

migraine. Other less hazardous AEDs have included this warning since the early 1980s, including Defendants' own anti-seizure drugs trimethadione (Tridione) and paramethadione (Paradion), which contained a BLACK BOX warning stating: "BECAUSE OF ITS POTENTIAL TO PRODUCE FETAL MALFORMATIONS AND SERIOUS SIDE EFFECTS, [drug name] SHOULD ONLY BE UTILIZED WHEN OTHER LESS TOXIC DRUGS HAVE BEEN FOUND INEFFECTIVE…"

43. Many other AEDs approved prior to 1995 clearly warned that due to potential serious side effects, they should be prescribed only when patients' conditions had proven refractory to treatment with other drugs. Examples include:

a) phenacemide (Phenurone) - indicated only for seizures "refractory to other drugs" or when "other available antiepileptics have been found to be ineffective in satisfactorily controlling seizures;"

b) mephenytoin (Mesantoin) - indicated for seizures "in those patients who have been refractory to less toxic anticonvulsants;" "should be used only after safer anticonvulsants have been given an adequate trial and have failed;"

c) methsuximide (Celontin) - indicated for control of absence (petit mal) seizures that are refractory to other drugs;" and,

d) felbamate (Febratol) - "recommended for use only in those patients who respond inadequately to alternative treatments."

44. Defendants failed to warn for over thirty years that Depakote should be completely contraindicated and/or a drug of last resort during pregnancy because Defendants sought to exploit the marketing potential for Depakote products, and did not want to risk secondary status for the marketing segment of women of childbearing years. In particular, Defendants fought to maintain market share during the three decades that Depakote in its various formulations had no

generic competition, heedless of the risk of teratogenicity when prescribed to women of childbearing years.

45. Multiple studies identify a strong, positive association between higher dosages of Depakote and congenital malformations in comparison to alternative AEDs. Yet, Defendants also failed to warn that high doses of Depakote increase the risk of fetal malformations compared to lower doses. To date, the Depakote label contains no warning of the dose-response relationship between valproate exposure and birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders and no recommendation to avoid higher doses in pregnant women or women likely to become pregnant.

46. Depakote's dangers and many years of inadequate labeling led to irreversible and devastating injuries to developing children before mothers or physicians even had a chance to discover the pregnancy.

47. Defendants knew or should have known they had a duty to warn doctors and patients long before that women who were taking Depakote should not get pregnant, and that women who might become pregnant should not take Depakote. This warning would have spared Plaintiffs a lifetime of pain and suffering, inordinate healthcare costs, severe emotional and physical distress, and loss of earning potential.

48. Depakote was and is a defective product, unreasonably dangerous in light of its nature and intended use. That defect existed when the product left Defendants' control and has been the proximate cause of injuries to Plaintiffs, whose injuries were caused by the use of Depakote in its intended or foreseeable manner or in the manner recommended by Defendants.

49. Defendants knew or should have known of the dangerous condition of Depakote, but failed to adequately warn or instruct physicians and consumers of the risks, dangers, and proper uses of the drug.

50. Defendants have breached their duty of reasonable care and their express and implied warranties, and have made affirmative misrepresentations as well as misrepresentations by omission, all in connection with the design, testing, manufacture, marketing, and/or labeling of Depakote.

51. As a direct and proximate result of the acts and omissions of Defendants, children were born with spina bifida, heart defects, autism and other autism spectrum disorders, lower IQ, neural tube defects, birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders. The injured children continue to suffer permanent injury, pain, loss of normal life, and other non-economic damages.

52. As a direct and proximate result of the aforesaid acts of and/or omissions by Defendants, the injured children have:

a) suffered severe and permanent injuries, which they will be forced to endure for the remainder of their lives;

b) suffered physical impairment and disfigurement;

c) suffered physical pain and suffering;

d) suffered mental pain and suffering;

e) suffered loss of enjoyment of life;

f) incurred substantial costs for medical care in the past, and will, in reasonable medical probability, incur substantial costs for medical care in the future;

g) suffered a loss of earnings and of future earning capacity; and,

h) incurred attorneys' fees and expenses of litigation related to this action.

Case-Specific Facts

53. Ann Scholz was prescribed Depakote for migraines, bipolar disorder, and possibly related to seizure activity.

54. Ms. Scholz took Depakote as prescribed starting in approximately 2002.

55. Ms. Scholz was taking Depakote as prescribed when she conceived B.P. in mid-September 2007 and continued to take Depakote as prescribed through November 12, 2007 (approximately eight weeks into the first trimester).

56. Ms. Scholz resumed taking Depakote in February 2008 while still pregnant.

57. B.P. was born in June 2008.

58. Depakote injured B.P. in utero and caused multiple birth defects, some of which may still be unknown. Furthermore, the extent of some of B.P.'s birth defects may not be fully known.

59. At present, B.P. suffers from the following birth defects that were caused by in utero exposure to Depakote: pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention deficit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

60. Ann Scholz was unaware of the severe cognitive dangers posed to B.P. by taking Depakote during pregnancy.

61. Plaintiff would not have taken Depakote if she understood the grave dangers it posed to her unborn child.

62. The ramifications caused by B.P.'s impairments will likely grow in scope and magnitude during B.P.'s entire lifetime.

63. B.P.'s conditions are permanent, life-long, and debilitating mental conditions.

64. B.P.'s conditions have deprived Plaintiff Ann Scholz of B.P.'s services, companionship, and society, and will continue to deprive her of those benefits.

65. Plaintiff B.P.'s conditions have caused stress, mental anguish, and suffering to Plaintiffs.

66. As a direct and proximate result of the acts of and/or omissions by Defendants, Plaintiffs have suffered the following injuries and damages:

a) bodily injury, disfigurement, conscious pain, suffering, mental anguish, mental suffering, embarrassment, shame, loss of enjoyment of life, shortened life expectancy, loss of association, loss of earnings, loss of profits, and loss of salary;

b) reasonable and necessary expenses for the medical treatment rendered to Plaintiffs in the past and that will be medically probable in the future;

c) permanent mental and physical impairment;

d) future economic damages during the age of minority and beyond the age of 18, including lost wages of Plaintiffs; and

e) costs of this suit.

Discovery Rule and Tolling Allegations

67. Defendants actively concealed information and actively misled Plaintiffs regarding Depakote's dangers, particularly the dangers of death and lifelong injury from birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

68. Defendants continue to actively conceal information and continue to actively mislead Plaintiffs, Plaintiffs' physicians, and the general public.

69. Defendants failed to disclose a known defect and affirmatively misrepresented that Depakote was safe for its intended use. Further, Defendants actively concealed the true risks associated with the use of Depakote.

70. Plaintiffs, the parents of the injured children, and/or the prescribing physicians had no knowledge that Defendants were engaged in the wrongdoing alleged herein.

71. Because of Defendants' concealment of and misrepresentations regarding the true risks associated with Depakote, Plaintiffs, the parents of the Injured Children, and/or the prescribing physicians could not have reasonably discovered Defendants' wrongdoing or the relationship

between Depakote and the injured children's birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders at any time prior to the commencement of this action.

72. As alleged herein, Defendants' fraudulent misrepresentations, fraudulent omissions, reckless misrepresentations, reckless omissions, negligent misrepresentations, and negligent omissions tolled the running of any statute of limitations.

73. Where applicable, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or, through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, the nature of the defective product, and the tortious nature of the wrongdoing that caused the injury.

74. Despite diligent investigation by Plaintiffs, Plaintiffs did not know the cause of their injuries, the nature of the defective product, or the tortious nature of Defendant's wrongdoing until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under the appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statute of limitations period.

75. The running of the statute of limitations in this case should also be tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions from Plaintiffs and/or their physicians, of the true risk associated with the product. As a result of Defendants' fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware and could not have known or learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct, proximate result of Defendants' wrongful acts and omissions.

76. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitation, including equitable tolling, estoppel, delayed discovery, the discovery rule, and fraudulent concealment.

77. Furthermore, the running of the statute of limitations is tolled where Plaintiffs are under the disability of minority status.

78. Therefore, Plaintiffs timely filed this action.

Causes of Action

Count One
Defective Design

79. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

80. At all times relevant, Defendants had a duty to manufacture, test, market, advertise, label, distribute, and sell Depakote so that it was reasonably safe for its foreseeable use.

81. Due to design defects, at the time Depakote left the control of Defendants and was sold, it contained one or more conditions that rendered it defective and unreasonably dangerous in light of its nature and intended use.

82. The Depakote manufactured and/or supplied by Defendants and to which Plaintiffs were exposed was defective in design, and/or formulation in that when it left the hands of Defendants, the foreseeable risks (particularly risks of birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders to unborn children) exceeded the benefits associated with the design and/or formulation of this product.

83. The Depakote manufactured and/or supplied by Defendants was defective in design and/or formulation in that it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

84. The dangers presented by Depakote are so great that reasonable health care professionals would not prescribe its use by pregnant women or women who may become pregnant if they knew of the risks.

85. The dangers presented by Depakote are so great that reasonable consumers—such as Plaintiffs—would not use Depakote when they were pregnant or might become pregnant if they knew of the risks.

86. At all times, Plaintiffs used Depakote in the manner intended, recommended, or reasonably foreseeable by Defendants, particularly based on Depakote's indications and/or Defendants' marketing of Depakote.

87. There were and are no other reasonable, secondary causes of Plaintiffs' injuries and damages other than the use of Depakote.

88. Defendants are strictly liable for injuries resulting from the defective design of their product.

89. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Two
Failure to Warn

90. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

91. The Depakote marketed, sold, and supplied by Defendants and to which Plaintiffs were exposed was defective in its marketing and labeling in that Defendants knew or should have known of its dangers and risks when taken by women who were pregnant or might become pregnant, but failed to adequately warn or instruct Plaintiffs, physicians, consumers, and the general public of the nature and extent of those risks.

92. The Depakote marketed, sold, and supplied by Defendants and to which Plaintiffs were exposed was defective in its marketing and labeling in that Defendants knew of should have known of its dangers and risks when taken by women who were pregnant or might become pregnant, as well as knew the means for reducing or eliminating those dangers and risks, but failed to adequately warn or instruct Plaintiffs, physicians, consumers, and the general public of those risks or means of reducing or eliminating the risks.

93. The Depakote marketed, sold, and supplied by Defendants was defective in marketing in that Defendants represented to the public that the product was safe and had qualities that it, in fact, did not have.

94. Had Plaintiffs known of Depakote's potential for causing deleterious, permanent damage to their children, they would not have taken Depakote.

95. Defendants are strictly liable for injuries resulting from their failure to warn.

96. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Three
Failure to Test

97. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

98. At all times relevant, Defendants had a duty to test Depakote so that it was reasonably safe for its foreseeable use.

99. Defendants failed to properly test Depakote to discover its potential for causing deleterious, permanent, and profound effects to unborn children.

100. The dangers presented by Depakote are so great that reasonable health care professionals would not prescribe its use by pregnant women or women who may become pregnant if they knew of the risks.

101. Defendants are strictly liable for injuries resulting from their failure to test.

102. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Four
Negligence

103. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

104. Defendants owed Plaintiffs and all consumers a duty of reasonable care in how they designed Depakote, manufactured Depakote, tested Depakote, and warned of Depakote's dangers.

105. Defendants breached their duty of care by designing, manufacturing, testing, and labeling Depakote in a manner that was dangerous to women who were pregnant or might become pregnant.

106. A reasonable manufacturer would or should have known that Depakote's risks are unreasonably greater than necessary and/or than other similar products.

107. The dangers presented by Depakote are so great that reasonable health care professionals would not prescribe its use by pregnant women or women who may become pregnant if they knew of the risks.

108. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Five
Gross Negligence

109. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

110. Defendants owed Plaintiffs and all consumers a duty of reasonable care in how it designed Depakote, manufactured Depakote, tested Depakote, and warned of Depakote's dangers.

111. Defendants breached their duty of care by designing, manufacturing, testing, and labeling Depakote in a manner that was dangerous to women who were pregnant or might get pregnant.

112. A reasonable manufacturer would or should have known that Depakote's risks are unreasonably greater than necessary and/or than other similar products.

113. Defendants consciously and voluntarily disregarded the risks to Plaintiffs and consumers in how they designed, manufactured, tested, and marketed Depakote, particularly in that they allowed pregnant women and women who might become pregnant to take Depakote in spite of its grave risks to their unborn children.

114. Defendants knew or should have known of Depakote's high instance of birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders, so its breaches were wanton and willful and evince Defendants' blatant, callous, and indifferent conduct towards Plaintiffs and consumers in general.

115. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Six
Fraud by Concealment

116. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

117. Defendants had a duty to disclose certain concealed facts, which include those dangers of which they knew, particularly those dangers so grave they would cause birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders in patients' unborn children.

118. Defendants disclosed some limited facts about Depakote's contraindications, but did not include those grave dangers that form the basis of this suit. This partial disclosure created a duty to fully disclose all Depakote's dangers to avoid misleading Plaintiffs and the public.

119. On information and belief, Defendants knew Depakote had the potential to cause profound birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders and actively concealed this until recently.

120. Defendants did not disclose that Depakote could lead to serious birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

121. If Ann Scholz had known of the information Defendants fraudulently concealed, they would not have taken Depakote before or during the pregnancy.

122. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Seven
Fraudulent Misrepresentation

123. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

124. Defendants had a duty to accurately represent certain material facts, which include those dangers of which they knew, particularly those dangers so grave they would cause birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders in patients' unborn children.

125. Through their silence and through their statements, Defendants misrepresented Depakote's safety to Plaintiff and the general public by failing to indicate it could cause grave danger to unborn children.

126. Defendants did not disclose that Depakote could lead to serious birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

127. Defendants knew or should have known Depakote had the potential to cause profound birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders and fraudulently misrepresented it as safe for pregnant women and women who might become pregnant.

128. If Plaintiff Ann Scholz had known of the information Defendants fraudulently misrepresented, she would not have taken Depakote before or during the pregnancy.

129. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder;

autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Eight
Negligent Misrepresentation

130. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

131. Defendants had a duty to accurately represent certain material facts, which include those dangers of which they knew, particularly those dangers so grave they would cause birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders in patients' unborn children.

132. Through their silence on the issue and through their statements, Defendants misrepresented Depakote's safety to Plaintiff and the general public by failing to indicate it could cause grave danger to unborn children.

133. Defendants did not disclose that Depakote could lead to serious birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

134. Defendants knew or should have known Depakote had the potential to cause profound birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders and were negligent in misrepresenting it as safe for pregnant women and women who might become pregnant.

135. If Plaintiff Ann Scholz had known of the information Defendants misrepresented, she would not have taken Depakote before or during the pregnancy.

136. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Nine
Breach of Express Warranty

137. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

138. Through their advertising, statements to the medical community, statements to the general public, marketing, and labeling, Defendants created express warranties that Depakote was safe and effective.

139. At the time they made these warranties, Defendants had knowledge or should have had knowledge that Depakote was not as safe or effective as its warranties promised.

140. Depakote does not conform to the express warranties created by Defendants in that it is dangerous to unborn children when taken by the mother and less effective than promised.

141. Plaintiffs relied on Defendants' warranties when deciding to take Depakote and would not have taken Depakote if they knew the warranties were false and the product was actually profoundly dangerous to her unborn child.

142. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder;

autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Ten
Breach of Implied Warranty

143. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

144. By selling Depakote, Defendants impliedly warranted the product was merchantable, including: that Depakote would pass without objection in the trade; that it would be of average quality; that it would be fit for its ordinary purpose and use; that it would be packaged and labeled properly; and that it would conform to the promises made in the marketing, packaging, and labeling of the product.

145. Depakote is dangerous to unborn children when taken by the mother and less effective than promised. As such, it would not pass without objection in the trade, is not of average quality (particularly when compared with other medications), is not fit for its ordinary purpose and use as a prescription drug, was not labeled in a way to warn consumers of its grave dangers, and did not conform to is marketing, packaging, and labeling promises of being safe for consumption.

146. At the time they sold Depakote, Defendants had knowledge or should have had knowledge that Depakote was not merchantable.

147. Plaintiff Ann Scholz relied on Defendants' warranties when deciding to take Depakote and would not have taken Depakote if she knew the product was not merchantable and was actually profoundly dangerous to her unborn child.

148. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating conditions including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Eleven
Intentional—or Grossly Negligent—Infliction of Emotional Distress

149. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

150. In ignoring Depakote's risks and not disclosing Depakote's risks to pregnant women and would-be mothers, Defendants acted in an extreme and outrageous manner.

151. Defendants should have known and/or did know that their conduct could cause and would cause emotional distress to parents who took Depakote and the children who suffered birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders as a result.

152. Depakote's dangers caused a risk of illness and bodily harm to Plaintiffs and actually did cause illness and bodily harm to Plaintiffs.

153. Defendants intentionally caused, or recklessly disregarded the risks of causing, the emotional distress associated with having and raising children with birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

154. Plaintiffs have suffered severe emotional distress from finding out that B.P.'s conditions were preventable and were caused by Depakote, and in raising B.P., such as having to deal with

B.P.'s pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

155. Defendants' outrageous conduct in not disclosing Depakote's risks is the actual and proximate cause of Plaintiffs' distress.

156. As a direct and proximate result of Defendants' wrongful actions, Plaintiffs have suffered emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Twelve
Negligent Infliction of Emotional Distress

157. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

158. Defendants owed a duty to act with reasonable care in the design, manufacturing, and marketing/labeling of Depakote.

159. Defendants breached their duties by releasing to the public a product that was inherently dangerous to unborn children and by not warning pregnant women or women who might get pregnant of the risks.

160. Defendants should have known and/or did know that their conduct could cause and would cause emotional distress to parents who took Depakote and the children who suffered birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders as a result.

161. Depakote's dangers caused a risk of illness and bodily harm to Plaintiffs and actually did cause illness and bodily harm to Plaintiffs.

162. Defendants' breaches caused B.P.'s permanent, profound, and debilitating impairments including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

163. B.P.'s condition—and knowledge of its preventability—caused emotional distress in Plaintiffs. Therefore, as a direct and proximate result of Defendants' wrongful actions and breaches, Plaintiffs suffered emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Count Thirteen
(Loss of Consortium)

164. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

165. As a direct and proximate result of Defendants' wrongful actions, B.P. suffers from permanent, profound, and debilitating disorders and impairments including pervasive developmental disorder; autism; developmental delay; bipolar disorder; attention defecit disorder / hyperactivity disorder combined; and a seizure disorder for which he now must take Depakote.

166. B.P.'s conditions have diminished or deprived Plaintiff Ann Scholz of B.P.'s services, companionship, and society and will likely continue to cause diminishment or deprivation of B.P.'s services, companionship, and society for the remainder of their lives.

167. Defendants' wrongful actions directly and proximately caused the loss of services, companionship, and society.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

Punitive Damages Allegations

181. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiffs and other Depakote victims and for the primary purpose of increasing its profits from sales of Depakote. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of them.

182. Prior to some or all Depakote sales, Defendants knew Depakote caused death and lifelong injury from birth defects, congenital malformations, cognitive impairment, and neurobehavioral disorders.

183. Prior to some or all Depakote sales, Defendants knew of adverse events, internal and external studies, and other relevant data indicating Depakote's dangers but failed to disclose these and even actively concealed them.

184. Defendants, through their officers, directors, managers, and agents, knew Depakote was dangerous and presented a substantial and unreasonable risk of harm to Plaintiffs but hid this and pushed forward with sales nonetheless.

185. Defendants' conduct was so despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants

with willful and conscious disregard for the safety of Plaintiffs, entitling Plaintiffs to punitive and exemplary damages.

Prayer for Relief

WHEREFORE, Plaintiffs and each of them pray for judgment against Defendants, jointly and severally, in an amount in excess of Seventy-Five Thousand Dollars in compensatory damages each, and in excess of One Million Dollars in punitive damages each, in such an amount as the jury may award, for attorney fees, costs, interest, and any other relief that this Honorable Court sees as just and equitable.

March 6, 2018.

Respectfully Submitted,

/s/ James G. O'Brien
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Counsel for Plaintiffs B.P. by his next friends Randolph H. Krings and Susan L. Matson-Krings and Ann Scholz

Jury Demand

Plaintiffs hereby request a trial by jury on all triable issues.

/s/ James G. O'Brien
James G. O'Brien (Ohio 0088460, Cal. 308239)

Counsel for Plaintiffs B.P. by his next friends Randolph H. Krings and Susan L. Matson-Krings and Ann Scholz